

U.S. Patent Application Serial No. 10/527,090  
Amendment filed November 2, 2006  
Reply to OA dated August 14, 2006

### **REMARKS**

Claims 1-36 are pending in this application. An amendment is proposed canceling claims 4, 10 and 22 without prejudice or disclaimer, and amending claims 1, 7, 11, 13, 19, 23, 25-26, 28-29, 31-33 and 34-35. Upon entry of this amendment, claims 1-3, 5-9, 11-21 and 23-36 will be pending.

No new matter is added by this amendment. Support for the amendments to the claims is discussed below. Applicant submits that this Response is fully responsive to the final Office action dated August 14, 2006.

### **Summary of Telephone Interview**

Applicant's agent, Daniel Geselowitz, telephoned Examiner Chowdhury on September 21, 2006. Applicant noted that the Examiner states in the summary that claims 1-36 are rejected, but that in the five stated rejections, there is no rejection of claim 5, 11, 17 or 23.

The Examiner agreed that there was no stated rejection for these claims, and that it would appear that claims 5 and 17 are allowable, and that claims 11 and 23 would be allowable if rewritten in independent form. Claims 11 and 23 have been rewritten in independent form, incorporating the limitations of their respective base claims.

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**Claims 25-26, 28-29, 31-32, and 34-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite and vague for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.** (Office action page 3, second paragraph)

The Examiner states that the hybridizing solution recited in the claims actually includes "50% formamide" and not "50% formaldehyde."

The Examiner is correct in this regard, and the rejection is overcome by the amendments to claims 25-26, 28-29, 31-32, and 34-35, correcting "50% formaldehyde" to --50% formamide--. The specification at page 7, line 15, is also amended in this regard.

As the Examiner has noted, 50% formamide is commonly used in stringency buffers, while 50% formaldehyde is not. Applicant submits that this was clearly a clerical mistake in the specification, and the correction to the well known stringency buffer composition does not represent new matter.

**Previous rejection of claims 1-3, 6-9, 12-15, 18-21 and 24 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained.** (Office action page 3, third paragraph)

Reconsideration of the rejection is respectfully requested in view of the proposed claim amendments. Claims 1, 7, 13 and 19 have been amended to require that the structural gene

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comprises the sequence set forth in SEQ ID NO: 1. Support for this amendment may be found, for example, in claims 4, 10 and 22, which have been canceled without prejudice or disclaimer.

Applicant notes that the Examiner had withdrawn the previous rejection under 35 U.S.C. 112, first paragraph, of claims 4, 5, 10, 11, 16, 17, 22 and 23, in response to the previous amendment amending these claims to comprise SEQ ID NO: 1 or SEQ ID NO: 2.

**Previous rejection of claims 1-3, 6-9, 12-15, 18-21, and 24 under 35 U.S.C. 112, first paragraph, on scope of enablement, is maintained. (Office action page 5)**

Reconsideration of the rejection is respectfully requested in view of the amendments to the claims. As noted above, claims 1, 7, 13 and 19 have been amended to require that the structural gene comprises the sequence set forth in SEQ ID NO: 1.

The Examiner states that the recited of transglutaminase genes are so broad as to encompass any transformant of *S. mobaraensis* or *S. lividans* comprising any gene encoding any wild type transglutaminase from *S. mobaraensis*, and that the scope of the method claims is not commensurate with the enablement provided by the disclosure. Claim 1 is amended to incorporate the limitation of claim 4, claim 7 to incorporate the limitation of claim 10, and claim 19 to incorporate the limitation of claim 22. The structural gene is therefore limited to the sequence set forth in SEQ ID NO: 1, which is clearly enabled.

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**Previous rejection of claims 13-14, 16, 18-19, 20, 22 and 24 under 35 U.S.C. 102(e) as being anticipated by Taguchi et al. (WO 01/29187 A1, ...) is maintained, and new claims 31-36 are rejected under 35 U.S.C. 102(e) as being anticipated by Taguchi et al. as the reasons given in previous office action and discussed below. (Office action page 7)**

The rejection of claims 13-14, 16, 18-19, 20, 22, 24, and 31-36, is respectfully traversed, and reconsideration of the rejection is requested.

The Examiner states that:

“Taguchi et al. further disclose the cloning of the cDNA in expression vector, which includes a transcriptional terminator derived from *Streptomyces azureus* (tsr gene comprises terminator) and producing transformant *S. lividans* comprising the expression vector containing the sequence of a transglutaminase gene and transformed *S. lividans*.”

The Examiner specifically indicates that the shuttle vector pUJ-MTG, used in Taguchi, comprises the tsr gene, which comprises a streptomyces specific termination signal sequence, newly citing Pulido et al. (1987). Pulido (1987) is a short abstract that refers to plasmid PIJ702.

Applicant notes, however, that the claims require: “a promoter and a terminator **acting on the structural gene**” of transglutaminase. The shuttle vector pUJ-MTG disclosed by Taguchi et al. contains the tsr gene, and the tsr gene comprises a streptomyces-specific termination signal sequence. However, this termination signal sequence acts on the tsr gene itself. In other words, this termination signal sequence is not used for a transcription of the transglutaminase gene (MTG) in the shuttle vector. This may be seen from the configuration of the shuttle vector in Fig. 1 of Taguchi et al.

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In contrast, the terminator recited in claims 13-14, 16, 18-19, 20, 22 and 24 acts on the structural gene of transglutaminase. This is not taught or suggested in Taguchi et al.

**Previous rejection of claims 1-2, 4, 6-8, 10 and 12 under 35 U.S.C. 103(a) as being unpatentable over Taguchi et al. (WO 01/29187 A1, ...) is maintained and newly added claims 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taguchi et al. as reasons discussed in previous office action and is now discussed below. (Office action page 10)**

The rejection is respectfully traversed, and reconsideration is requested.

The Examiner reiterates that Taguchi discloses using the gene from *S. mobaraensis* with the natural promoter, and using the to make a transformant of *S. lividans*. The Examiner acknowledges at the bottom of page 11: "Taguchi et al. ... do not disclose transforming *S. mobaraensis* comprising sequence of a transglutaminase gene."

Finally on page 12, line 8, the Examiner restates the motivation for the proposed modification of the reference:

**"Furthermore, contrary to applicant's arguments a skilled artisan would have been motivated to express the transglutaminase gene of Taguchi et al. in *S. mobaraensis* because native regulatory factors, which are present in *S. mobaraensis* would activate the transcription by acting on natural promoter to produce said transglutaminase protein in increased amounts than other host cell. ..."**  
(emphasis added)

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Applicant respectfully submits that this motivation for combining the references is improper. Applicant had previously argued that this motivation is based on the assumption that using the same bacterium as the source of the gene and the host would give an increased level of expression. Applicant maintains the previously argued position that there is **no basis** for this assumption in the disclosure of Taguchi et al., and that the Examiner had given no basis in the general art for this assumption. Applicant notes that the Examiner has not responded to Applicant's arguments in this regard from the Amendment dated May 5, 2006, and **that the Examiner has not cited any basis** in the general art for this assumption.

Applicant also notes, as argued above in regard to the rejection under 35 U.S.C. 102(e), that Taguchi et al. does not provide the "terminator acting on the structural gene" of transglutaminase.

Claims 1-2, 4, 6-8, 10 and 12, are therefore not obvious over Taguchi et al.

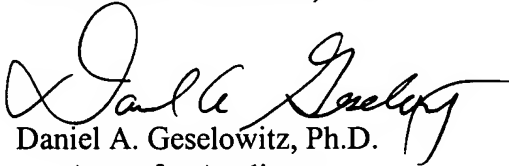
If, for any reason, it is felt that this application is not now in condition for allowance, the Examiner is requested to contact the Applicant's undersigned agent at the telephone number indicated below to arrange for an interview to expedite the disposition of this case.

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In the event that this paper is not timely filed, the Applicants respectfully petitions for an appropriate extension of time. Please charge any fees for such an extension of time and any other fees which may be due with respect to this paper, to Deposit Account No. 01-2340.

Respectfully submitted,

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